next succeeding day which is not a Saturday, Sunday or a Federal holiday. Accordingly, the present action is filed timely within the one-month shortened statutory period for responding to the Office.

REMARKS

I. Election/Restriction

A restriction requirement was issued, and the pending claims were divided into the following groups of inventions:

Group I: claims 1, 2, 5 and 19-21, drawn to a tablet, class 424, subclass 465;

Group II: claims 1, 3, 27 and 28, drawn to a capsule, class 424, subclass 451;

Group III: claim 14, drawn to a layer tablet, class 424, subclass 472;

Group IV: claim 15-18, 22-26, 29, 30 and 39, drawn to a tablet with coated pellets, class 424, subclass 462;

Group V: claim 35, drawn to a composition, class 514, subclass 428; and

Group VI: claims 36 and 37, drawn to a blister pack, class 206, subclass 531.

Applicants elect the invention of Group I, with traverse, for examination purposes.

II. Traversal of the Restriction Requirement

The Examiner alleges that Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1. The Examiner states that the requirement of unity of invention, as defined by PCT Rule 13.2, is not fulfilled because the claims do not share the same special technical feature necessary to specify a contribution over the prior art. In this regard, the Examiner concludes that "[t]he tablet, pellet and coated pellets are known in the art" and, therefore, there is no special distinguishing feature distinguishing the claims over the prior art.

Applicants respectfully disagree and traverse the restriction requirement for the following reasons.

Firstly, Annex B of the Manual of Patent Examining Procedure ("MPEP") provides the following:

> (c) **Independent and Dependent Claims.**
> Unity of invention has to be considered in the first place ***only in relation to the independent claims in an international application and not the dependent claims.*** By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc). (Emphasis added).

Except for process claim 28 in Group II and process claims 29-30 in Group IV, all of the remaining claims of Groups I-IV are dependent claims and depend, either directly or indirectly, on claim 1. Moreover, all of the claims of Groups I-IV are classified in the same class 424. Therefore, at least with respect to the claims of Groups I-IV and excluding process claims 28-30, the Examiner is required in view of Annex B of the MPEP to consider unity of invention only in relation to claim 1.

Claim 1 is directed to an oral pharmaceutical dosage form. Specifically, the claimed dosage form comprises a H^+, K^+-ATPase inhibitor and a gastric antisecretory prostaglandin analogue compound. It is this combination of active ingredients in one fixed dosage form which is the special technical feature linking the inventions of Groups I-VI and defining the inventions of Groups I-VI over the prior art.

Applicants do not disagree with the Examiner's observation that tablets, capsules, pellets and coated pellets are known dosage forms. However, prior to the claimed invention, oral dosage forms comprising a H^+, K^+-ATPase inhibitor, a gastric antisecretory prostaglandin, and optionally a calcium channel blocking agent, in the same dosage form were unknown. In this regard, the Examiner's attention is directed to the International Preliminary Examination Report ("IPER") which issued in the International application No. PCT/SE99/02315 from which the subject U.S. national stage application derives. As noted in the IPER, the claimed combination of H^+, K^+-ATPase inhibitor and a gastric antisecretory prostaglandin in one fixed dosage form fulfills the requirements of novelty and inventive step:

> The invention differs from the cited documents in that the two active compounds are in one fixed unit dosage form. According to the applicant, omeprazole, as well as other H^+, K^+-ATPase inhibitors, is susceptible to degradation/transformation in acidic and neutral media, and can not be included together with misoprostol which is an oily, greasy compound in a single unit form unless special measures have been made.
>
> Therefore, claims 1-30 and 33-37 are considered to fulfill the requirements of novelty, inventive step and industrial applicability.

The Examiner has not cited any contrary prior art supporting the allegation that the pharmaceutical dosage forms of Groups I-IV are not new. Accordingly, Applicants rely on Annex B of the MPEP and the IPER in support of their position that the independent claims avoid the prior art and all of the claims of Groups I-IV are linked by the same inventive link, i.e.,

the claimed combination of H^+, K^+-ATPase inhibitor and a gastric antisecretory prostaglandin in one fixed dosage form.

With specific regard to process claim 28 of Group II, process claims 29-30, composition claim 35 of Group V and blister pack claims 36-37 of Group VI, these claims are also linked to each other and to the claims of Groups I-IV by the same special technical feature.

It appears incongruous that the Examiner has reached a different conclusion regarding unity of invention in view of PCT Rules 13.1 and 13.2 whereas the requirement of unity of invention was satisfied by the related PCT application. Accordingly, Applicants respectfully submit that the Examiner is unfairly and unjustly applying a more rigorous standard in evaluating unity of invention in the national stage application than the standard in the related PCT application.

Therefore, it is Applicants' position that the claims of Groups I-VI, as originally filed, satisfy the requirements of PCT Rules 13.1 and 13.2. There is an inventive link between all of the claims of Groups I-VI. All of the independent claims and their respective dependent claims share the same special technical feature, i.e., the combination of a H^+, K^+-ATPase inhibitor, a gastric antisecretory prostaglandin, and optionally a calcium channel blocking agent, in one fixed dosage form. It is this feature which defines the contribution of Groups I-VI over the prior art. For all of the foregoing reasons, withdrawal of the restriction requirement is requested.

CONCLUSIONS

Groups I-VI share a special technical feature and, therefore, the Examiner is respectfully requested to withdraw the restriction requirement and retain the claims of Group I-VI in the subject application for searching and examination. In the event that the restriction requirement is made final, Applicant reserves the right to file one or more divisional applications directed to the non-elected claims.

Any fees due in connection with communication should be charged to Deposit Account No. 23-1703.

Dated: April 29, 2002

Respectfully submitted,

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